

REMARKS

Claims 7-11 are currently pending in the present application. Claims 1-6, 12-17 are withdrawn from consideration. In lieu of the withdrawn claims, new claims 18-31 have been added in lieu of the withdrawn claims.

Applicant has carefully studied the outstanding Office Action. The present response is intended to be fully responsive to all points of rejection and/or objection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested. No new matter has been added by the amendments, if any, to the specification. Applicant respectfully requests withdrawal of the Examiner's rejections in view of the foregoing amendments and following remarks.

CLAIM REJECTIONS – 35 U.S.C. § 102

Claim 7-11

The Examiner has rejected claims 7-11 under 35 U.S.C. § 102, as being anticipated by U.S. Patent No. 5,697,904 issued to Raines et al. (hereafter "Raines"). Specifically, the Examiner has stated:

In the specification and the figures, Raines discloses the apparatus as claimed by the applicant. Specifically, Raines discloses a valve for a medical fluid device comprising first and second inlet ports 91 and 93, an outlet port 92 wherein the two inlet ports are arranged at an acute angle from one another (see column 15, lines 10-54, FIG 15). **The inlet ports feature pressure-activated check valves that allow fluid flow in the direction of the outlet, preventing reverse fluid flow.**

With regard to applicant's claim limitations drawn to the operation of the claimed valve (allowing fluid to pass in particular directions, relieving pressure, presentation of an indicator, adjusting opening pressures), such limitations are held to be recitations of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. (Emphasis Added)

It is the Applicant's position that Raines fails to teach each and every limitation of the claimed invention. Specifically, Raines fails to teach the following:

- “[a second inlet] wherein the second inlet allows fluid to pass from a source into the valve toward the outlet in the event that negative pressure in the line reaches a predetermined level”

First, it is well-settled that the “features of an apparatus may be recited either structurally or functionally.” *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Here, Raines fails to teach a second inlet that “allows fluid to pass from a source into the valve toward the outlet in the event that negative pressure in the line reaches a predetermined level.” As permitted by case precedent, the Applicant has chosen to recite the claim limitation in terms of function rather than structure. This is distinguished from “intended use” where a claim recitation simply states the use of the apparatus. Here, the functional language imposes particular structural requirements on the apparatus, all of which are fully supported by the specification. Specifically speaking, in the Applicant's claimed invention, the second inlet only allows fluid to pass through the second inlet when negative pressure in the line reaches a predetermined level. Raines fails to disclose a structure that anticipates the claimed behavior.

Assuming, for purposes of this response, the first inlet is shown by element 91 in Raines, and therefore the second inlet would be shown by element 93. Only Figures 18, 19A, and 19B of Raines disclose a device wherein a first and second inlet (albeit not necessarily the inlet(s) claimed by the Applicant) having an angle between the two inlets of less than 90 degrees (as recited by the Applicant). Meanwhile, in Raines, the second inlet (93) is taught as a free-flowing “inlet.” The Examiner has not identified any figure or written description within the specification of Raines that suggests restricting fluid flow in any manner, much less so as to only allow fluid flow through the second inlet into the valve when the line experiences negative pressure (nor out of the second inlet from the valve when the line experiences positive pressure as recited in dependent claim 10). Meanwhile, the specification of the present invention teaches that the second inlet may use “an umbrella valve or other one-way valve that responds to negative pressure on the side of the valve closest to the line []” to achieve the desired function. (See paragraph [0030])

For these reasons, absent any further suggestion within the specification of Raines that can be specifically identified by the Examiner, the Applicant strongly believes Raines fails to anticipate the present invention, specifically claim 7.

Claims 8-11

With respect to claim 8, the claim provides the following limitation “wherein the second inlet relieves negative and positive pressure in the line without introducing air into the line.” This limitation is an example of reciting a claim limitation in terms of function. This is distinct from “intended use.” The aforementioned claim limitation requires that the second inlet allow fluid flow into the valve when negative pressure (at a certain level) is present in the line AND the valve must not allow air to enter the line. There is no suggestion within Raines that the second inlet 93 have any such properties nor does Raines teach any structure that accomplishes the recited function. Meanwhile, the Applicant’s specification clearly suggests structural embodiments that would provide the recited limitations. Therefore, not only is claim 8 not a recitation of “intended use,” but Raines fails to teach a structural limitation that anticipates the limitation of claim 8.

For purposes of clarity, the Applicant has submitted a claim amendment with respect to claim 8 to further clarify the limitation in functional terms by removing the words “and positive” from the claim. The relief of positive pressure is not recited until claim 10. The limitation is not submitted to overcome any rejection of the claim by the Examiner, and in fact the Applicant believes the current language standing alone is sufficient to overcome the currently pending rejection of claim 8 by the Examiner.

With respect to claim 9, the applicant claimed the following limitation: “wherein the valve presents a visual indicator when it allows fluid to flow from a source other than the patient into the first line.” This is clearly a structural limitation claimed in terms of function. The claim limitation requires a structure within the claimed invention having such a visual indicator, and such appropriate visual indicators have been described within the Applicant’s specification, but not Raines. For this reason, the claim language is not a form of “intended use” as suggested by the Examiner. However, for the sake of clarity, the Applicant has amended the language to better illustrate that the valve “further comprises a visual indicator” rather than the use of the term

“presents.” It is respectfully urged that the Examiner consider that this amendment removes any possible suggestion that claim 9 is directed solely toward intended use.

With respect to claim 10, the applicant claims “wherein the second inlet allows fluid to pass from the line to the source in the event that positive pressure in the line reaches a predetermined level of positive pressure.” The addition of the words “of positive pressure” has been added to distinguish the claim limitation from the “predetermined level” of negative pressure recited in claim 7. Raines fails to disclose any structure that achieves the same function as that in the present invention. In fact, Raines fails to disclose any sort of regulation on the second inlet that would control the flow of fluid.

Finally, with respect to claim 11, there is no structure within Raines that regulates the flow of fluid through the second inlet based on the level of positive pressure within the line. As an extension of that argument, Raines cannot teach that the predetermined level of positive pressure can be adjusted. For this reason, claim 11 is in condition for allowance.

It is respectfully requested, that claim 7-11 are in condition for allowance in their present forms. The Examiner has not identified any structural limitations within Raines that anticipates the limitations of claims 8-11 so any further rejections directed toward those claims limitations cannot be made final. Further the additional claims 18-31 are all believed to be in condition for allowance.

CONCLUSION

Applicant has fully responded to the Examiner's rejections. It is respectfully urged that the subject application is patentable over references cited by Examiner and is now in condition for allowance. Applicant requests consideration of the application and allowance of the claims. If there are any outstanding issues that the Examiner feels may be resolved by way of a telephone conference, the Examiner is cordially invited to contact David W. Carstens at 972.367.2001.

The Commissioner is hereby authorized to charge any additional payments that may be due for additional claims to Deposit Account 50-0392.

Respectfully submitted,

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